

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)(KMW)

**CERTIFICATION OF JOHN R. DAVIS IN SUPPORT OF *DAUBERT*
MOTION TO EXCLUDE CLASS CERTIFICATION OPINIONS OF
ERIC SHEININ, PH.D.**

I John R. Davis, certify as follows:

1. My name is John R. Davis. I am an attorney at law in Austin, Texas, and a partner with the law firm of Slack Davis Sanger, LLP, and serve as Court-appointed Plaintiffs' Executive Committee ("PEC") counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' Motion to Exclude Testimony of Mylan Expert Eric Sheinin, Ph.D.
2. Attached hereto as **Exhibit 1** to the Motion is a true and correct copy of certain excerpts of Dr. Sheinin's March 21, 2022 deposition.
3. Attached hereto as **Exhibit 2** to the Motion is a true and correct copy of Dr. Sheinin's January 12, 2022 Expert Report, as marked and used at Dr. Sheinin's deposition.
4. Attached hereto as **Exhibit 3** is a true and correct copy of the United States Food and Drug Administration's ("FDA") November 5, 2019 Warning Letter to Mylan, as

- marked and used at both Derek Glover's Rule 30(b)(6) deposition and at Dr. Sheinin's deposition.
5. Attached hereto as **Exhibit 4** to the Motion is a true and correct copy of the ICH M7 Guidance Regarding the Assessment and Control of DNA Reactive (Mutagenic) Impurities to Limit Potential Carcinogenic Risk, as marked and used at Dr. Sheinin's deposition.
 6. Attached hereto as **Exhibit 5** to the Motion is a true and correct copy of the FDA's March 14, 2019 Drug Master File ("DMF") Deficiency Letter issued to Mylan, as marked and used at Dr. Sheinin's deposition.
 7. Attached hereto as **Exhibit 6** to the Motion is a true and correct copy of the FDA's Orange Book Preface, as marked and used at Dr. Sheinin's deposition.
 8. Attached hereto as **Exhibit 7** to the Motion is a true and correct copy of *Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-4431, 2021 WL 4077563, at *3 (D.N.J. Sept. 8, 2021).
 9. Attached hereto as **Exhibit 8** to the Motion is a true and correct copy of *SEC v. Ambassador Advisors, LLC*, -- F. Supp. 3d --, *5 (E.D. Pa. Dec. 21, 2021).
 10. Attached hereto as **Exhibit 9** to the Motion is a true and correct copy of Mylan's Impurities Section of its Valsartan API Drug Master File, as marked and used at Dr. Sheinin's deposition.

Executed this 3rd day of May, 2022.

/s/ John R. Davis
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